Program

VACCINE TECHNOLOGY II

June 1-6, 2008

Grande Real Santa Eulalia Resort

Albufeira, Algarve, Portugal

Co-Chairs:

Barry C. Buckland, Ph.D. Research Vice President, Bioprocess R&D, Merck & Co., Inc.

John G. Auniņš, Ph.D. Executive Scientific Director, Bioprocess R&D, Merck & Co., Inc.

Paula Marques Alves, Ph.D. Principal Investigator Animal Cell Technology Laboratory, ITQB/IBET

Kathrin U. Jansen, Ph.D. Sr. Vice President Early Phase Programs, Wyeth Vaccine Research



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Organizing Committee

Manuel Carrondo, Professor and CEO, IBET, Portugal Manon Cox, COO, Protein Sciences Corp., USA Matthew Croughan, Professor, Keck Graduate Institute, USA Anne De Groot, CEO, EpiVax, Inc., USA Emilio Emini, Executive Vice President, Wyeth Pharmaceuticals, USA Nathalie Garcon, Vice President, GlaxoSmithKline Biologicals, Belgium Phillip Gomez, Principal, PRTM, USA Michael Hoare, Professor, University College London, UK David Kaslow, Vice President, Merck & Co., Inc., USA Phil Minor, Head, Division of Virology, NIBSC, UK Octavio Ramirez, Professor, Institute of Biotechnology, UNAM, Mexico **Rino Rappuoli**, Vice President, Novartis Vaccines, Italy Jerald Sadoff, CEO, Aeras Global TB Vaccine Foundation, USA Volker Sandig, Vice President, ProBioGen AG, Germany George Siber, Consultant, USA John Vose, Consultant, France David Weiner, Professor, University of Pennsylvania School of Medicine, USA

Sunday, June 1, 2008

03:30 pm – 05:30 pm	Registration
05:30 pm – 06:00 pm	Welcome and conference overview
06:00 pm – 07:00 pm	The Challenge of Providing an Effective, but Technically Complex, Vaccine to the Developing World Emilio Emini, Wyeth Pharmaceuticals, USA
07:00 pm – 08:00 pm	Reception
08:00 pm – 10:00 pm	Opening Dinner and entertainment

IMPORTANT ANNOUNCEMENTS

- Audiotaping, videotaping and photography of presentations are strictly prohibited.
- Speakers Please leave at least 5 minutes for questions and discussion.
- Please do not smoke at any conference functions.
- Turn your cellular telephones to vibrate or off during technical sessions.
- Be sure to make any corrections to your name/contact information on the Master Participant List or confirm that the listing is correct. A corrected copy will be sent to all participants after the conference.

Monday, June 2, 2008

07:00 am – 08:30 am	Breakfast
08:30 am – 10:30 am	Session I: Immune System Function and Its Quantitation (Sponsored by Merck & Co., Inc.) Session Chair: David Weiner, University of Pennsylvania School of Medicine
08:30 am – 09:00 am	Human Monoclonal Antibodies and Analytic Vaccinology Antonio Lanzavecchia, Institute for Research in Biomedicine, Switzerland
09:00 am – 09:30 am	Utilizing Influenza Vaccination to Rapidly Clone High Affinity Human Monoclonal Antibodies and to Test the Concept of Original Antigenic Sin Jens Wrammert, Emory University School of Medicine, USA
09:30 am – 10:00 am	Anti-viral Immune Responses in Lymph Nodes Ulrich H. von Andrian, Harvard Medical School, USA
10:00 am – 10:30 am	Immunological Response to new DNA vaccines David Weiner, University of Pennsylvania School of Medicine, USA
10:30 am – 11:00 am	Break (Sponsored by Bioreliance)
11:00 am – 11:30 am	The First Clinical Efficacy Trial of an Adenovirus Type 5-Based HIV-1 Vaccine: The STEP Study Danilo Casimiro, Merck & Co., Inc., USA
11:30 am – 12:00 pm	Quality Issues: The Good-Enough Vaccine Phil Minor, NIBSC, UK
12:00 pm – 12:45 pm	New Methods for Detecting Adventitious Agents David Onions, BioReliance Corporation, USA
12:45 pm – 01:30 pm	Lunch
01:30 pm – 03:30 pm	Ad hoc sessions, free time
03:30 pm – 06:00 pm	Session II: Virus and Replicon Vectored Vaccines (Sponsored by GE Healthcare - WAVE Products Group) Session Chairs: Manuel Carrondo, IBET Alexander von Gabain, Intercell AG
03:30 pm – 04:00 pm	Towards a Therapeutic Hepatitis C Vaccine – a Preclinical and Clinical Learning Curve Alexander von Gabain, Intercell AG, Austria
04:00 pm – 04:30 pm	Delivery Devices and Approaches for Pre-Clinical and Clinical HIV Immunization Britta Wahren, Karolinska Institute and Swedish Institute for Infectious Disease Control (SMI), Stockholm, Sweden
04:30 pm – 05:00 pm	Flavivirus Capsid Deletion Mutants as a New Vaccine Approach Christian Mandl, Medical University Vienna, Austria

Monday, June 2, 2008 (continued)

05:00 pm – 05:30 pm	Viral Vectors – Coupling Innate Signals to Antigen Expression and Presentation Peter Liljeström, Karolinska Institute Stockholm, Sweden
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05:30 pm – 06:00 pm	VEEV Replicon-Based Vaccines used in Heterologous Prime Boost Strategies Induce Lifelong Protection from Prostate Cancer and Therapy of Cervical Cancer in Mice and Robust Cell-Mediated Immunity in Rhesus Macaques W. Martin Kast, University of Southern California, USA
06:00 pm – 06:30 pm	Break (Sponsored by Pall Life Sciences)
06:30 pm – 08:30 pm	Session III: Emergent & Emergency Vaccines Session Chair: Manon Cox, Protein Sciences Corp.
06:30 pm – 07:00 pm	Efficient and Economical Influenza Vaccines Alan Shaw, VaxInnate, USA
07:00 pm – 07:30 pm	Flublok, A High Dose Recombinant Influenza Vaccine Manon Cox, Protein Sciences, USA
07:30 pm – 08:00 pm	Challenges and Solutions for the Next Generation of Vaccines: Development of Cell Culture-based Live Attenuated Influenza Vaccine Jonathan Liu, MedImmune, Inc., USA
08:00 pm – 08:30 pm	Toward the Development of a SARS Vaccine Jeffrey Ulmer, Novartis Vaccines and Diagnostics, USA
08:30 pm – 09:30 pm	Dinner
09:30 pm – 11:00 pm	Poster Reception

Tuesday	<u>, June</u>	3, 2008

07:00 am - 08:30 am	Breakfast
08:30 am – 10:30 am	<u>Session IV: Conjugate Vaccines</u> Session Chair: George Siber , Consultant
08:30 am – 09:00 am	Analytical and Manufacturing Challenges in Preparation of Bacterial Polysaccharide Conjugates Carl Frasch, Frasch Biologics Consulting, USA
09:00 am – 09:30 am	Development of Validated Assays for Measuring the Human Antibody Response to Polysaccharide Conjugate Vaccines Helena Käyhty, National Public Health Institute, Finland
09:30 am – 10:00 am	The Human Immune Response to Polysaccharides and Conjugates David Goldblatt, University College London, UK
10:00 am – 10:30 am	The Impact of Polysaccharide Conjugate Vaccines George Siber, Consultant, USA
10:30 am – 11:00 am	Break (Sponsored by Artelis)
11:00 am – 11:30 am	Regulatory Issues Associated with the Development of a Comprehensive Meningococcal Vaccine Ian Feavers, NIBSC, UK
11:30 am – 12:00 pm	TB Vaccine Development and Manufacturing Jerald Sadoff, Aeras Global TB Vaccine Foundation, USA (Being presented by Walter Kallaur)
12:00 pm – 12:30 pm	Evaluating Novel Cell Substrates for use in Vaccine Manufacture Phil Krause, FDA/CBER, USA
12:30 pm – 01:00 pm	Epitode Driven GAIA HIV Vaccine Development: An Update Annie De Groot, EpiVax, Inc., USA
01:00 pm – 02:00 pm	Lunch
02:00 pm – 04:00 pm	Session V: Adjuvants & Formulation Session Chair: Nathalie Garçon, GlaxoSmithKline Biologicals
02:00 pm – 02:30 pm	The Improved ISCOMATRIX® Adjuvant Debbie Drane, CSL Ltd., Australia
02:30 pm – 03:00 pm	Adjuvanted Plasmid DNA-Based Vaccines Alain Rolland, Vical Inc., USA
03:00 pm – 03:30 pm	Exploiting Glycoengineered Yeast for the Development of Next Generation Vaccines Robert Davidson, GlycoFi, USA
03:30 pm – 04:00 pm	Enhancing Vaccine Immunogenicity Through use of CpG TLR9 Agonists and Other Adjuvants Risini Weeratna, Coley Pharmaceutical Group, Canada

Tuesday, June 3, 2008 (continued)

04:00 pm	<i>Ad hoc</i> sessions, free time for those not going on optional excursion. Those going on optional excursion should meet at 4:20 in hotel lobby for 4:30 departure.
04:30 pm	Optional Excursion/Dinner to Tavira where one can visit the medieval castle and old Moorish town. Dinner will be on your own and the buses will return to the hotel after dinner. Participants not going on the optional excursion will have dinner on their own either at the hotel or in a local restaurant.

Wednesday, June 4, 2008

07:00 am - 08:30 am	Breakfast
08:30 am – 11:00 am	Session VI: Characterization of Complex Biologicals Session Chairs: Robert Sitrin, Merck & Co., Inc.
08:30 am – 09:00 am	Quality Assessment of Cervarix [™] , GSK'S Cervical Cancer Vaccine, Manufactured with the Baculovirus Expression Vector System (BEVS) Marguerite Deschamps, GlaxoSmithKline, Belgium
09:00 am – 09:30 am	Characterization of Conjugate Vaccines Rasappa Arumugham, Wyeth Vaccines R&D, USA
09:30 am – 10:00 am	Characterization of Adenoviral Vector-Based Vaccines Katey Einterz Owen, Merck & Co., Inc., USA
10:00 am – 10:30 am	Focus on Aggregation: Causes, Impact & Characterization John Philo, Alliance Protein Laboratories, USA
10:30 am – 11:00 am	Developing In-Vitro Potency Assays to Monitor Process Development and Stability for Subunit Vaccine Ying Zhang, Wyeth Vaccines R&D, USA
11:00 am- 11:30 am	Break (Sponsored by GlaxoSmithKline Biologicals)
11:30 am – 12:00 pm	Challenge of Filing 4 New Vaccines at Once Keith Chirgwin, Merck & Co., Inc., USA
12:00 pm – 12:30 pm	PATH: Narrowing the Immunization Gap John Boslego, PATH, USA
12:30 am – 01:00 pm	Viral Vectors for Genetic Vaccination: Strategies, Vector Design and Production Juan Asenjo, University of Chile, Chile
01:00 pm – 02:00 pm	Lunch
02:00 pm – 04:00 pm	Ad hoc sessions, free time
04:00 pm – 06:10 pm	<u>Session VII: VLP's & Inactivated Vaccines</u> (Sponsored by Probiogen) Session Chairs: Octavio Ramirez, UNAM, Mexico Kathrin U. Jansen, Wyeth Vaccine Research
04:00 pm – 04:30 pm	Controlling <i>in vitro</i> Assembly of Virus-like Particles: From Theory to Example(s) Adam Zlotnick, University of Oklahoma Health Sciences Center, USA
04:30 pm – 05:00 pm	Virus-Like Particles as Vaccine Platforms Bryce Chackerian, University of New Mexico, USA
05:00 pm – 05:30 pm	Alternate Rotavirus Vaccines: Inactivated Virus and VLPs Margaret Conner, Baylor College of Medicine, USA

Wednesday, June 4, 2008 (continued)

05:30 pm – 05:50 pm	Towards a Respiratory Syncytial Virus Vaccine Using Recombinant F Protein Transiently Expressed in Mammalian Cells Sophie Nallet, École Polytechnique Fédérale de Lausanne (EPFL), Switzerland
05:50 pm – 06:10 pm	A Selective Recovery Methodology for the Clarification of Lipid-Envelope Virus-like Particles from S. Cerevisiae Gaik Sui Kee, University College London, UK
06:10 pm – 06:40 pm	Break
06:40 pm – 07:10 pm	Considerations for use of the "Animal Efficacy Rule" Karen Goldenthal, Consultant, USA
07:10 pm – 07:40 pm	De-risking Vaccine Development: Correlates of Success Fiona MacLaughlin, The Wellcome Trust, UK
07:40 pm – 08:00 pm	AGE1.CR – A Well Characterized Cell Substrate Designed for Production Vector Based Vaccines Volker Sandig, ProBioGen AG, Germany
08:00 pm – 09:15 pm	Dinner
09:15 pm – 11:00 pm	Poster Reception

<u>Thursday, June 5, 2008</u>

07:00 am – 08:30 am	Breakfast
08:30 am –10:30 am	Session VIII: Veterinary Vaccines: Lessons to Learn for Human Vaccine Development (Sponsored by Merial Ltd.) Session Chair: Robert Nordgren, Merial Limited
08:30 am -09:00 am	Emerging Diseases, Zoonoses and Vaccines to Control Them Paul-Pierre Pastoret, World Organization for Animal Health, France
09:00 am -09:30 am	Avian Influenza Vaccine Development: Application Technology Platforms, Field Use and Predictors of Protection David E. Swayne, US Department of Agriculture, USA
09:30 am –10:00 am	Use of Alternate Hosts in the Modeling of Immune Profiling and Vaccine Recognition Lorne Babiuk, University of Saskatchewan, Canada
10:00 am –10:30 am	Use of Plasmid DNA Vaccine to Treat Melanoma in Dogs Jedd Wolchok, Memorial Sloane Kettering Cancer Center, USA (Being presented by Robert Nordgren, Merial Limited)
10:30 am- 11:00 am	Break
11:00 am– 01:00 pm	<u>Session IX: Manufacturing of Vaccines</u> Session Chairs: John G. Auniņš, Merck & Co., Inc. Paula Marques Alves, ITQB/IBET
11:00 am- 11:30 am	Process Intensification for Large Scale Manufacturing Issues Jose Castillo, Artelis, Belgium
11:30 am- 12:00 pm	Multivalent Vaccines for Control and Eradication of FMD M. Susana Levy, Biogenesis-Bago S.A., Argentina
12:00 pm– 12:30 pm	Manufacturing and Regulatory Challenges During the Approval of the First Gene Therapy for Food Animals Henry Hebel, VGX Pharmaceuticals, USA
12:30 pm– 12:50 pm Process	Intensifying the Productivity of a Recombinant AD35 Manufacturing Using the PER.C6® Cell Substrate Alfred Luitjens, Crucell, Netherlands
12:50 pm– 01:10 pm	Affinity Chromatography of Cell Culture Derived Vaccinia Virus Michael Wolff, Max Planck Institute for Dynamics of Complex Technical Systems, Germany
01:10 pm – 02:10 pm	Lunch
02:10 pm – 04:10 pm	Ad hoc sessions, free time

Thursday, June 5, 2008 (continued)

04:10 pm – 05:30 pm	Session IX: Manufacturing of Vaccines (cont'd)
04:10 pm – 04:30 pm	Trouble-Shooting Fermentation and Primary Recovery Manufacturing Issues in Order to Optimize Antigen Expression Used as Vaccine Candidates Against Infectious Diseases Timothy Lee, Sanofi Pasteur, Canada
04:30 pm – 04:50 pm	Technology Transfer and Process Scale-Up Bo Arve, Wyeth Pharmaceuticals, USA
04:50 pm – 05:10 pm	Predictive Modeling in Rotavirus-like Particles Production: Improving Upstream and Downstream Processing Design Tiago Vicente, IBET, Portugal
05:10 pm – 05:30 pm	Implementation of Disposable Technology in Vaccines Manufacturing: An Approach to Extractables/Leachables Studies Hélène Pora, Pall Life Sciences, France
05:30 pm – 06:00 pm	Break
06:00 pm – 08:00 pm	<u>Session X: Vaccines in Developing Countries</u> Session Chair: Barry Buckland, Merck & Co., Inc.
06:00 pm – 06:30 pm	The Development of an Inactivated JE Vaccine for Endemic Countries Mahima Datla, Biological E, India
06:30 pm – 07:00 pm	Chickenguniya incidence and Vaccine Technology Krishna Ella, Bharat Biotech, India
07:00 pm – 07:30 pm	Vaccine Development for Developing Countries – Regulatory Approach in the European Union Manfred Haase, Consultant, Germany
07:30 pm – 08:00 pm	Developing Vaccines for Neglected Diseases Douglas Holtzman, Bill & Melinda Gates Foundation, USA
08:30 pm – 11:00 pm	Banquet & Closing

Friday, June 6, 2008

07:00 am - 10:00 am

Breakfast and departure (hotel check-out is noon)

Poster Presentations

- 1. **Metabolism of avian designer cells during influenza and MVA production** Verena Lohr, Max Planck Institute for Dynamics of Complex Technical Systems, Germany
- Capturing of cell culture derived influenza viruses by sulphated cellulose membranes A promising pseudo-affinity method for influenza vaccine production Lars Opitz, Max Planck Institute for Dynamics of Complex Technical Systems, Germany
- Anti-apoptotic action of one protein isolated from Lonomia Obliqua and the mitochondrial participation Ronaldo Zucatelli Mendonca, Instituto Butantan, Brazil
- 4. Influenza A virus-like particles as vaccine: comparison and evaluation of different strategies Florian Krammer, Institute for Applied Microbiology, Austria
- Rabies virus glycoprotein (RYGP) expression in drosophila S2 cells and in BHK-21 cell infected by recombinant semliki forrest virus for vaccine purpose Pereira CA, Instituto Butantan, Brazil
- 6. **Towards a recombinant vaccine for heartwater** Nontobeko Thema, Agricultural Research Council - Onderstepoort Veterinary Institute, South Africa
- Cryo-electron microscopy as a tool for imaging, characterization and structural analysis of biological solutions Clint Potter, NanoImaging Services, USA
- 8. Insect cells as an efficient platform for the production of AAV-based vaccines Marc G. Aucoin, University of Waterloo, Canada
- 9. Engineering of an E. coli host for production of plasmid biopharmaceuticals Diana M. Bower, Massachusetts Institute of Technology, USA
- Rapid deployment plasmid production: combining inducible high yield fermentation process with novel autolytic plasmid DNA purification Aaron E. Carnes, Nature Technology Corporation, USA
- 11. Modified E. Coli B, A superior producer of plasmid DNA compared with E. Coli K Joseph Shiloach, Biotechnology Lab NIDDK, USA
- 12. Immunogenic display of diverse peptides on virus-like particles of RNA phage Ms2 David S Peabody, University of New Mexico School of Medicine, USA
- 13. Novel techniques for characterization of double and triple-layered rotavirus-like particles Maria Candida M. Mellado, IBET/ITQB-UNL, Portugal
- Host strain influences on supercoiled plasmid DNA Production in E. Coli; implications for efficient design of Large scale processes Sin Yee Yau, The Advanced Centre for Biochemical Engineering, UK
- 15. **Insights into the effects of culture media and metabolites on adenovirus production** Chun Fang Shen, Biotechnology Research Institute, Canada
- 16. Novel adenovirus 5 vaccine delivery platform which overcomes pre-existing immunity to AD Frank R. Jones, Etubics Corporation, USA
- 17. Fermentation strategies for the production of recombinant protein antigens in E. Coli Willie Sun, Wyeth Pharmaceuticals, USA

18. Critical process parameter to control productivity in helper-dependent adenoviral vector production

Amine Kamen, Biotechnology Research Institute, Canada

- 19. **Production of yellow fever virus in vero cells grown in serum-free medium** Leda R. Castilho, Federal University of Rio de Janeiro, Brazil
- 20. Screening of DNA vaccines prototypes encoding antigen targeting sequences against sleeping sickness

Gabriel A. Monteiro, Institute for Biotechnology and Bioengineering, Portugal

- 21. On the design and production of more stable and efficient plasmid DNA vectors Duarte Miguel F Prazeres, IBB-Institute for Biotechnology and Bioengineering, Portugal
- Vp7 and Vp4 genotyping of bovine group a rotavirus in México. Towards the development of a recombinant vaccine
 William A. Rodríguez-Limas, Universidad Nacional Autónoma de México, México
- 23. **293 cells: An alternative cell line for PPRV production** Paula Marques Alves, ITQB-UNL/IBET, Portugal
- 24. Assessment of the thermal stability of Cervarix ™ Diane Doucet, GlaxoSmithKline Biologicals, Belgium
- 25. The influence of elevated oxygen partial pressure on specific virus productivities in an influenza vaccine process Andreas Bock, Max Planck, Germany
- 26. Rotavirus-Like Particle Production: Mathematical Modeling Rational Approach for Process Development António Roldão, IBET/ITQB-UNL, Portugal
- 27. Development of a cell culture production platform for cold-adapted live attenuated influenza vaccine (CAIV) strains of Flumist®: effects and interactions of medium components, trypsin, and different influenza viruses in process productivity
 Luis Maranga, MedImmune Vaccines, USA
- 28. Development of a cell culture production platform for cold-adapted live attenuated influenza vaccine (CAIV) Strains of Flumist®: accelerated development of a fully disposable Phase I clinical manufacturing process Luis Maranga, MedImmune Vaccines, USA
- 29. Capillary electrophoresis for the differentiation of double-layered and triple-layered rotavirus-like particles

Laura A. Palomares, Instituto de Biotecnología. Universidad Nacional Autónoma de Mexico, Mexico

- Differential expression and functional analysis of e. ruminantium proteins: identification of potential antigens for a subunit heartwater vaccine Isabel Marcelino, ITQB/IBET, Portugal
- Characterization of a cancer vaccine based on very small size proteoliposome (VSSP) obtained by different formulation processes.
 Vladmir Peña, Center of Molecular Immunology, Cuba
- 32. The Silver Anniversary of Clinical Protein production from recombinant CHO cell culture Matt Croughan, Rathmann Professor, Keck Graduate Institute, USA
- 33. A cell-culture-based platform for viral vaccine production for humans Marina Etcheverrigaray, Universidad Nacional del Litoral, Argentina

- 34. Rapid mycoplasma testing: The HYMY[™] assay combines amplification of viable mycoplasmas in broth culture with signal detection by quantitative polymerase chain reaction (QPCR) David Onions, BioReliance Corporation, USA
- 35. Comparison of dengue-2 virus production in vero cells under serum-free and serum-containing conditions

Erica A. Schulze, Federal University of Rio de Janeiro, School of Chemistry, Brazil

36. Perfusion process for human and animal viral vaccine production in a single use stirred tank bioreactor

Nicholas Havelange, Artelis, Belgium

- Exploiting lymphatic transport and complement activation in th1 stimulating nanoparticle vaccines Jeffrey A. Hubbell, Melody A. Swartz, Ecole Polytechnique Fédérale de Lausanne (EPFL), Switzerland
- 38. **MDCK-based influenza production using Cytodex 3 in a wave bioreactor** Johanna Norberg, GE Healthcare Bio-Sciences AB, Sweden
- 39. Protection induced by pneumococcal surface protein a (pspa) is enhanced by conjugation to a streptococcus pneumoniae capsular polysaccharide Luciana C.C. Leite, Instituto Butantan, Brazil
- Biodistribution and toxicological safety evaluation of adenovirus type 5 vectored vaccines against ebola and marburg viruses Rebecca L. Sheets, Vaccine Research Center, NIAID/NIH, USA
- 41. Development of a universal influenza vaccine Walter E. Manger, Merck & Co., Inc., USA
- 42. Purification of retrovirus vector particles and identification of host-associated proteins by proteomic analysis Maria Mercedes Segura, Center of Animal Biotechnology and Gene Therapy (CBATEG), Spain
- 43. SPR Technology as a Powerful Tool to Accurately Determine Influenza Virus Concentration Camilla Nilsson, GE Healthcare Bio-Sciences AB, Sweden (presented by Johanna Norberg, GE Healthcare Bio-Sciences AB)
- 44. Protective Immune Responses to Pathogenic Influenza Using Consensus DNA Immunogens and Constant Current Electroporation Henry Hebel, VGX Pharmaceuticals, USA
- 45. Development of a BioVeris-based, Quantitative Immunoassay for Assessing the Quality of a Conjugate Vaccine Candidate Charlie Chen, Wyeth Research, USA